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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,131	11/30/2001	Daniel R. Soppet	PZ037P1C1	3384

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EXAMINER	
BRANNOCK, MICHAEL T	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 08/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/997,131	SOPPET ET AL.	
	Examiner	Art Unit	
	Michael Brannock	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *NA*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, 14, 15, 21, drawn to polynucleotides, host cells and methods of producing a polypeptide, classified in class 536, subclass 23.5.

II. Claims 11, 12, 16, drawn to polypeptides, classified in class 530, subclass 350.

III. Claim 13, drawn to antibodies, classified in class 530, subclass 388.22.

IV. Claim 17 and 24, drawn to methods of treatment, classified in class 514, subclass 2.

V. Claim 18, drawn to methods of diagnosis comprising detecting a polynucleotide, classified in class 435, subclass 6.

VI. Claim 19, drawn to methods of diagnosis comprising detecting a polypeptide, classified in class 435, subclass 7.2.

VII. Claims 20 and 22, drawn to methods of identifying binding partners of a polypeptide and biological activity of a polypeptide, classified in class 436, subclass 501.

VIII. Claim 23, drawn to non-antibody binding partners of a polypeptide, classification dependent on the chemical identity of the binding partner.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to <u>different</u> products, restriction is

deemed to be proper because these products appear to constitute patentably distinct inventions for the following reasons: Groups I-III and VIII are directed to products that are distinct both physically and functionally, and are not required one for the other, and are therefore patentably distinct. Further, the protein of Group II can be prepared by processes which are materially different from recombinant DNA expression of Group I, such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the DNA of Group I can be used other than to make the protein of Group II, such in the gene therapy or as a probe in nucleic acid hybridization assays. The protein of Group II can be used in materially different methods other than to make the antibody of Group III, such as in therapeutic or diagnostic methods (e.g., in screening). Although the antibody of Group III can be used to obtain the DNA of Group I, it can also be used in materially different methods, such as in various diagnostic (e.g., in as a probe in immunoassays or immunochromatography), or therapeutic methods. Although, the protein Group I can be used to identify the binding partner of Group VIII, the protein could also be used to produce the antibody of Group III. Although, the DNA of Group I can be used to produce the protein of Group I which can be used to identify the binding partner of Group VIII, the DNA could also be used to as a diagnostic probe. The binding partners of Group VIII are distinct from the protein and from the DNA because the binding partners could be obtained from sources other than those employing the protein of Group II or the DNA of Group I, such as from commercial vendors. Furthermore, the antibody of Group III is distinct from the non-antibody binding partner of Group VIII, because one is not required for the use of the other. Furthermore, the antibody of Group III is distinct from the binding partner (antagonist or agonist) of Group VIII,

because an antibody which binds to a protein does not necessarily alter the activity of the protein as required of an antagonist or agonist.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups IV-VII are directed to methods that are distinct both physically and functionally, and are not required one for the other. Group IV requires methods of treatment, which is not required by any of the other groups. Group V requires methods of detecting a nucleic acid, which is not required by any of the other groups. Group VI requires methods of detecting a protein, which is not required by any of the other groups. Group VII requires methods of assaying for binding partners, which is not required of any of the other groups.

The polynucleotides of Group I are related to the methods of Groups IV, V, VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Group I are patentably distinct from each of the methods of Groups IV, V, VII because the polynucleotides can be used in ways that are materially and functionally different than each of the methods because, as discussed above, each of the methods of Groups IV, V, VII are materially and functionally distinct from the others. Furthermore, the

polynucleotides of Group I and the methods of Group VI are patentably distinct because one is not required for the use of the other.

The polypeptides of Group II are related to the methods of Groups IV, VI and VII as product and process of use. In the instant case, the polypeptides of Group II are patentably distinct from each of the methods of Groups IV, VI and VII because the polypeptides can be used in ways that are materially and functionally different than each of the methods because, as discussed above, each of the methods of Groups IV, VI and VII are materially and functionally distinct from the others. Furthermore, the polypeptides of Group II and the method of Group V are patentably distinct because one is not required for the use of the other.

The antibodies of Group III are related to the methods of Groups IV, VI and VII as product and process of use. In the instant case the antibodies of Group III are patentably distinct from each of the methods of Groups IV, VI and VII because the antibodies can be used in ways that are materially and functionally different than each of the methods because, as discussed above, each of the methods of Groups IV, VI and VII are materially and functionally distinct from the others. Furthermore, the antibodies of Group III and the method of Group V are patentably distinct because one is not required for the use of the other.

The agonist and antagonist (binding partners) of Group VIII and the methods of Groups IV, VI and VII are related as product and process of use, and are patentably distinct because the agonist and antagonist of Group VIII can be used in ways that are materially and functionally different than the each of the methods of Groups IV, VI and VII because, as discussed above, each of the methods of Groups IV, VI and VII are materially and functionally distinct from the

others. Furthermore, the agonist and antagonist of Group VIII and the methods of Group VI are patentably distinct because one is not required for the use of the other.

Therefore, because these inventions are distinct for the reasons given above and because a search and examination of all the groups in one patent application would result in an undue burden, since the searches for the groups are not co-extensive, the classification is different, and the subject matter is divergent, restriction for examination purposes as indicated is proper.

Additionally, this application contains claims directed to the following patentably distinct species of invention: Polynucleotides and polypeptides having a sequence identifier in the form of SEQ ID NO: X. Each SEQ ID NO represents a structurally and functionally distinct molecule, the use of one not being required for the use of any other. Further, a search of one SEQ ID NO could not be relied upon to provide art that is anticipatory of any other, and to search more than one SEQ ID NO in a single application would be burdensome.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of polynucleotide (e.g. SEQ ID NO: 1) or polypeptide (e.g. SEQ ID NO: 57) for prosecution on the merits.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, Ph.D., can be reached at (571) 272-0961.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

August 2, 2004